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10/590,866	09/19/2006	Henry William Lupton	Q96748	8975
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SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER SMITH, FANGEMONIQUE A	
			ART UNIT 3736	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
USPTO@SUGHRUE.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,866	<b>Applicant(s)</b> LUPTON ET AL.	
	<b>Examiner</b> Fangemonique Smith	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 87-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 87-107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/28/06</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 87-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. At line 4 of claim 87, the pronoun "its" is used. However, one cannot be certain to what the pronoun is intended to refer. Hence, the claim is rendered unclear and indefinite. Upon rejection of claim 87, any claim depending from claim 87 is also rejected.

5. Regarding claims 90-95, 97 and 99-107, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Art Unit: 3736

6. Regarding claims 90, 92-95, 97, 100, 101, 103-105 and 107, the phrase "advantageously" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 90 recites the broad recitation "the leading edge portion extends in a direction at an angle in the range of 1° to 90° relative to an axial direction defined by the main central axis", and the claim also recites "the leading edge portion extends in a direction at an angle in the range of 30° to 90° relative to an axial direction defined by the main central axis" and "the leading edge portion extends in a direction at an angle of approximately 60° relative to an axial direction defined by the main central axis" which both are narrower statements of the original range/limitation.

Art Unit: 3736

8. Regarding claims 91, 92, 94, 96, 97, 99, 101 and 102, the phrase "alternatively" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

9. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 91 recites the broad recitation "the first surface portion of the terminal member is planar", and the claim also recites "the first surface portion of the terminal member is convex in a longitudinal direction relative to the main central axis"; "the first surface portion of the terminal member is concave in a longitudinal direction relative to the main central axis" and "the first surface portion of the terminal member is sequentially convex and concave in a longitudinal direction relative to the main central axis" which all are narrower statements of the original range/limitation. Upon rejection of claim 91, any claim depending from claim 91 is also rejected.

Art Unit: 3736

10. Claim 92 recites the limitation "a distal portion" in line 1. Prior to this recitation a distal leading edge portion is disclosed. It is unclear if the limitation intends to refer to the distal leading edge portion previously disclosed or if the limitation intends to introduce another distal portion, rendering the claim indefinite.

11. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 92 recites the broad recitation "the second surface portion of the terminal member is planar", and the claim also recites "the second surface portion of the terminal member is convex in a longitudinal direction relative to the main central axis"; "the second surface portion of the terminal member is concave in a longitudinal direction relative to the main central axis" and "the second surface portion of the terminal member is sequentially convex and concave in a longitudinal direction relative to the main central axis" which are all narrower statements of the original range/limitation.

Art Unit: 3736

12. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 93 recites the broad recitation "the first and second surface portions of the terminal member define an included angle in the range of 1° to 179°", and the claim also recites "first and second surface portions of the terminal member define an included angle in the range of 5° to 90°" and "the first and second surface portions of the terminal member define an included angle of approximately 15°" which both are narrower statements of the original range/limitation.

13. Regarding claim 95, the phrase "ideally" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

14. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP §

Art Unit: 3736

2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 95 recites the broad recitation "the third and fourth surface portions of the terminal member define an included angle in the range of 1° to 179°", and the claim also recites "third and fourth surface portions of the terminal member define an included angle in the range of 5° to 90°" and "the third and fourth surface portions of the terminal member define an included angle of approximately 15°" which both are narrower statements of the original range/limitation.

15. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131



Art Unit: 3736

USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 96 recites the broad recitation “the third surface portion of the terminal member is convex in a longitudinal direction relative to the main central axis”, and the claim also recites “the third surface portion of the terminal member is concave in a longitudinal direction relative to the main central axis” and “the third surface portion of the terminal member is sequentially convex and concave in a longitudinal direction relative to the main central axis” which are all narrower statements of the original range/limitation.

16. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 97 recites the broad recitation “the fourth surface portion of the terminal member is convex in a longitudinal direction relative to the main central axis”, and the claim also recites “the fourth surface portion of the terminal member is concave in a longitudinal direction relative to the main central axis” and “the fourth surface

Art Unit: 3736

portion of the terminal member is sequentially convex and concave in a longitudinal direction relative to the main central axis” which are all narrower statements of the original range/limitation.

17. The term "similar" in claims 100 and 103 is a relative term which renders the claim indefinite. The term "similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 100 is rejected.

***Claim Rejections - 35 USC § 102***

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

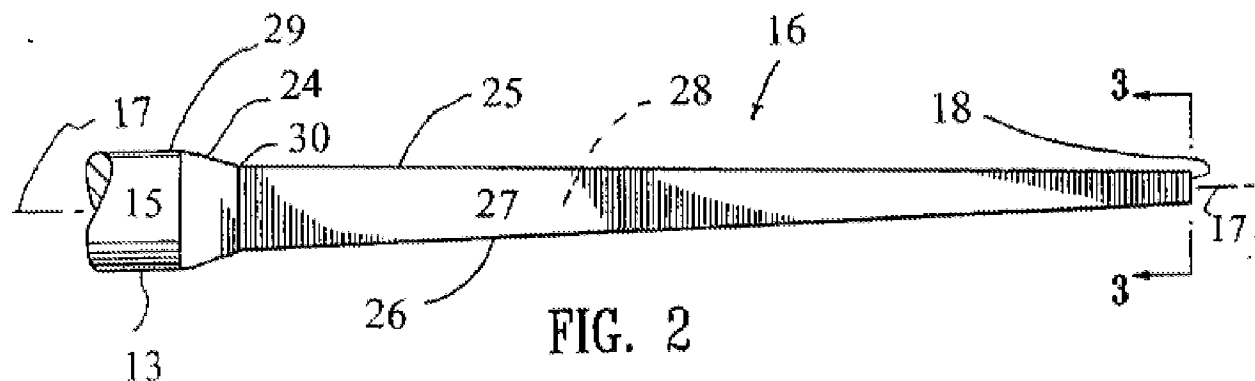
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

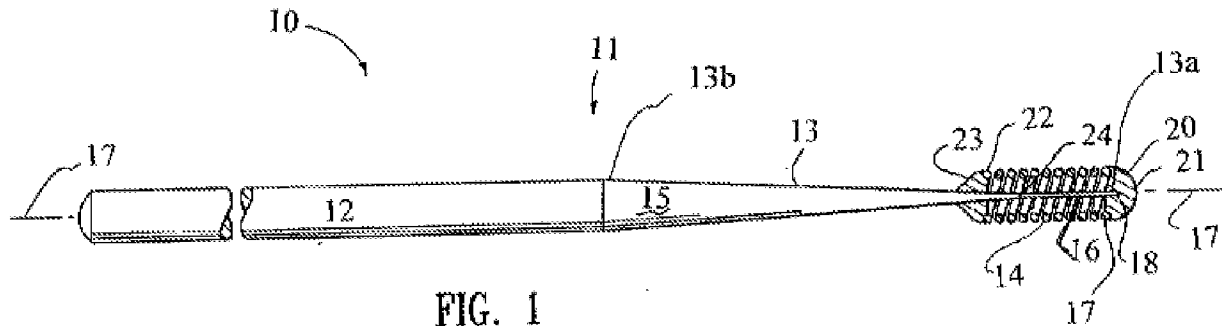
19. Claims 87-95, and 100-104 are rejected under 35 U.S.C. 102(e) as being anticipated by Jafari et al. (U.S. Patent Application Publication Number 2003/0013993).

In regard to claims 87-95 and 100-104, Jafari et al. disclose a guide wire having an elongate core member which extends between a proximal end and a distal end, and defines a longitudinally extending main central axis. The guide wire has a distal end which terminates in a terminal member extending axially from the guide wire. The terminal member of the Jafari et al. device tapers to a distal, elongated leading edge portion (Figure 2).

Art Unit: 3736



As shown above, the leading edge portion extends in a direction at an angle in the range of  $1^\circ$  to  $90^\circ$  relative to an axial direction defined by the main central axis. The Jafari et al. device further includes a first planar surface portion of the terminal member which converges towards an opposite second planar surface portion thereof towards the leading edge portion. The terminal member of the device includes a rectangular distal cross section with a circular proximal cross section. Jafari et al. disclose the first and second surface portions may also be concave (paragraph [0033]). Jafari et al. have first and second surface portions of the terminal member which are joined by spaced apart opposite third and fourth planar surface portions. The third and fourth surface portions of the terminal member are parallel to each other in an axial direction defined by the main central axis. Additionally, the maximum outer transverse cross-sectional area of the terminal member of the Jafari et al. device is substantially similar to the outer transverse cross-sectional area of the guide wire adjacent the terminal member (Figure 2). Jafari et al. disclose a helical coiled sleeve which extends along the core wire from the terminal member and terminates at a location intermediate the distal end and the proximal end of the core wire (Figure 1).



The terminal member of the Jafari et al. device is secured to the sleeve by brazing or soldering (paragraphs [0005]; [0025]). Jafari et al. further disclose the sleeve or engaging bore may be made of a radiopaque material.

### ***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 96-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jafari et al. (U.S. Patent Application Publication Number 2003/0013993) in view of Shabaz et al. (U.S. Patent Application Publication Number 2005/0065453).

In regard to claims 96-99, Jafari et al. disclose the features of the Applicant's invention as described above. Jafari et al. do not specifically disclose having curved third and fourth surfaces as part of the device. Shabaz et al. disclose a biopsy device which separates and collects tissue from a target site within a patient. The device disclosed by Shabaz et al. includes a probe

Art Unit: 3736

component having a penetrating distal tip with a first, second and third curved surface. Shabaz et al. disclose the penetrating distal tip also having a distal concave portion of a fourth surface portion of the tip. The leading edge portion of the tip disclosed by Shabaz et al. is radiused having a concave orientation from the first surface portion of the tip to the second surface portion of the tip. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a guide wire having an elongate core member which extends between a proximal end and a distal end, similar to that disclosed by Jafari et al., to include a third and fourth concave surface as a part of the tip design, similar to that disclosed by Shabaz et al., to allow penetration of the tip through occluding objects while gaining access to desired area.

22. Claims 105 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jafari et al. (U.S. Patent Application Publication Number 2003/0013993) in view of Hastings et al. (U.S. Patent Application Publication Number 2002/0019644).

In regard to claims 105 and 106, disclose the features of the Applicant's invention as described above. Jafari et al. do not specifically disclose the use of a magnetic material for guiding the device through to a desired target area. Hastings et al. disclose a guide wire device having a magnetic element located at the distal tip of the device to orient the tip as desired. The magnetic material is designed to facilitate directing the terminal member through a vascular system by way of a magnetic urging means located externally from the patient. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a guide wire having an elongate core member which extends between a proximal end and a distal end, similar to that disclosed by Jafari et al., to include a magnetic material located at the distal

Art Unit: 3736

tip of the device, similar to that disclosed by Hastings et al., to provide a mechanism which allows the user to orient the distal tip of the device in effort to access a desired target area.

23. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jafari et al. (U.S. Patent Application Publication Number 2003/0013993) in view of Wagner (U.S. Patent Number 5,135,483).

In regard to claim 107, Jafari et al. disclose the features of the Applicant's invention as described above. Jafari et al. do not specifically disclose using the guide wire in a re-canalising procedure. Wagner discloses a device and method for re-canalising a vascular occlusion in a human or animal subject. The device disclosed by Wagner includes method steps comprising urging a terminal member of a guide wire through an occlusion within the body of a patient. Wagner discloses using this procedure to remove occlusions from the lumen of the vessel. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a guide wire having an elongate core member which extends between a proximal end and a distal end, similar to that disclosed by Jafari et al., to include method steps of use which employs the device to remove occlusions from a body vessel, similar to that disclosed by Wagner, to clear arteries and veins of occluding material.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

Art Unit: 3736

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736